Docket No. 55591-RCE(71699)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Jeffrey J. Rade, et al.

U.S.S.N.: 09/863,803 Art Unit: 1632

FILED: May 22, 2001 Examiner: Li, Qian J.

FOR: GENETIC ENGINEERING OF VASCULAR GRAFTS TO RESIST DISEASE

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By: Patricia A. Barnes
Patricia A. Barnes

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LETTER

Applicants respectfully request consideration of the attached Request for Continued Examination (RCE) and entry of Response Under 37 CFR 1.116 mailed to the USPTO on July 11, 2003 ("Response"). Applicants wish to respond as follows to comments made by the USPTO in the Advisory Action dated July 30, 2003.

REMARKS

As an initial matter, Applicants gratefully acknowledge that upon entry of the claim amendments set forth in the Response, the Examiner will deem outstanding rejections under 102(e) and 103(a) as moot. Advisory Action at pg. 2.

However, Applicants must respectfully disagree that the claim amendments could not be considered without filing the instant RCE. Advisory Action at 2.

In particular, Applicants assume that the Office conducted a full and thorough search of the art relating to the claimed invention. In view of that search, it is not seen how amending the claims to recite more particular nucleic acids requires "further consideration". Applicants believe the amendment could have been considered by the Office in the prior case without any undue burden on the Examiner.

On page 2 of the Advisory Action, the Office indicated that notwithstanding entry of the Response, claims 1, 3-12, and 14-28 would stand rejected under 35 USC §112, first paragraph (written description and enablement) for reasons already of record. Applicants disagree with that position and respectfully request reconsideration.

With respect to the written description rejection, the Office has not shown that Applicants were not in possession of the claimed subject matter as of the application filing date. See the "Guidelines" in the Federal Register, Vol. 66, pp. 1099-1111, part IB at pg. 1105. What the Office has done in the Advisory Action is to review some references from the specification and allege that because they do not specify Applicant's functional fragments that the written description requirement has not been satisfied. Respectfully, that is not the correct inquiry. Instead, the Office should confirm that Applicants were in **possession** of the subject matter claimed **as of the application filing date**. Applicants have satisfied this requirement as described in the Response.

For instance, a variety of suitable TM molecules (full-length and suitable fragments) for use with the invention have been described. The phrase "functional

fragment" of TM has been precisely defined at pg. 17, lines 26 to 30, of the specification for instance.

Applicants specification also describes a range of EPCR and NF-kB inhibitor molecules that can be used with the claimed invention. Importantly, the phrase "functional fragment" of EPCR is specifically described at pg. 20, line 28 to pg. 21, line 2 of Applicants' specification.

Full-length and functional fragments of NF-kB inhibitor are fully described at pg. 22, lines 5-24. The phrase "functional fragment" of NF-kB inhibitor is specifically defined at pg. 22, lines 21-24.

In view of Applicants' detailed description of suitable TM, EPCR, and NF-kB agents for use in the claimed method including fragments, it is not seen how the instant written description rejection can withstand scrutiny. Clearly, Applicants' have shown that they were in possession of the claimed invention as of the application filing date.

In view thereof, reconsideration and withdrawal of the outstanding written description rejection are requested.

In view of the above, Applicants have also fully satisfied the "how to make" and "how to use" requirement of 35 USC §112, first paragraph.

On pg. 2 of the Advisory Action, the Office alleged that Kim et al admitted that "it was a surprise that the expression of EPCR was not reduced in the untreated grafts". Applicants cannot agree that this statement, even if true, illustrates unpredictability in this field. Advisory Action at pg. 2. Fairly read, the reference does not provide evidence, as

required by MPEP 2164.05a, that the authors recognized that invention of claim 1 and 24, as amended was not possible.

It is believed that the application is in condition for allowance, which action is earnestly solicited. Although it is not believed that any fee is needed to consider this submission, the USPTO is authorized to charge our deposit account no. **04-1105** should such fee be deemed necessary.

Respectfully submitted,

Date: 8 SEPT 03

By: _____

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